REMARKS

Claims 1 and 7-12 are pending. Claims 2-6 are canceled. Upon entry of this paper, claims 1 and 8 are amended, and new claim 13 is added.

Telephone Interview

Applicants' representatives acknowledge the Examiner's telephone call to Kenneth Sonnenfeld on April 11, 2007. The substance of the Examiner-initiated interview was a discussion of the claim language.

Support for Amendments

Upon entry of this paper, claims 1 and 8 are amended to include the phrase "identifies bacteria involved in the biosynthesis of ecteinascidin compounds" to indicate a function for the claimed nucleotides. Support for the phrase can be found in the specification as filed, for example at page 5, lines 8-11 and page 16, line 27, and Example 5.

Upon entry of this paper, new claim 13 is added. Support for claim 13 can be found in previous claims 8 and 9 from which claim 13 depends.

No new matter is entered.

No New Issues for Consideration

Applicants respectfully request entry of this paper as it presents no new issues for consideration. The amendments to claims 1 and 8 require no new issues for consideration because the functionality for the claimed polynucleotides has already been examined. The

amendment to add new claim 13 requires no new issues for consideration because claim 13 presents a subgenus from previously examined claim 9.

Rejection Under 35 U.S.C. § 112, 2nd paragraph

Claims 1 and 10-12 are rejected under 35 U.S.C. § 112, 2nd paragraph, for being indefinite. The Office Action states that the phrase "wherein said modification, variant or fragment thereof is capable of hybridising to the complement of SEQ ID NO: 1" is redundant because such a variant

> is by inherency capable of hybridising to the complement of SEQ ID NO:1, therefore it is unclear how said phrase provides any additional information about the invention

(Office Action, page 2, lines 13-15, emphasis in original). Applicants respectfully traverse the rejection on the basis that language with respect to hybridisation is sufficiently definite according to the statute, and on the basis that according to the MPEP, Examiners "should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement" (see MPEP 2173.02). However, in order to advance prosecution, Applicants amend claims 1 and 8 to remove the language with respect to hybridisation as suggested by the Examiner.

Rejection Under 35 U.S.C. § 112, 1st paragraph

Claims 1 and 7-12 are rejected under 35 U.S.C. § 112, 1st paragraph, for lack of enablement. The Office Action indicates that the claims are enabled for isolated DNA sequences consisting of or comprising DNA SEQ ID NO:1, but lack enablement

> for either SEQ ID NO:1 variants and homologs having at least 95% identity to SEQ ID NO:1 or fragments and probes comprising at least 5 or more bases of SEQ ID NO:1 or claimed homologs

> thereof wherein said fragments or probes are capable of hybridising to SEQ ID NO:1 or claimed homologs thereof

(Office Action, page 4, lines 10-16). Applicants thank the Examiner for indicating that the specification is enabling for isolated DNA sequences consisting of or comprising SEQ ID NO:1. With respect to the remaining scope of the claims, Applicants respectfully traverse.

The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright,* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). All that is necessary is that one skilled in the art be able to practice the claimed invention without undue experimentation, given the level of knowledge and skill in the art.

In this case, the manipulation of nucleic acid sequences is well known in the field of molecular biology. In addition, numerous examples of nucleic acid manipulation and analysis are provided by the specification, for example in Examples 1 and 2. Guidance on the performance of in situ hybridisation is provided in Example 4, and the results of hybridisation with a variety of probes are presented in Examples 4 and 5. Furthermore, Applicants are using art-recognized techniques and methodology. As stated in the specification, the

> [u]se of 16S rRNA gene sequences to identify bacteria **is now the standard procedure for analysis of bacteria** in environmental samples and has enabled much of the progress in the area of bacterial symbiosis

(see Specification, page 13, lines 9-13, emphasis added). The Office Action itself argues that hybridisation for sequences with 95% identity is an inherent attribute. Therefore, no further guidance is necessary or warranted in terms of which nucleotides are required within the 95% parameter required in claim 1 because hybridisation is the inherent function of the sequence used according to the art-recognized procedure for analysis of bacteria in environmental samples.

As a well-settled point of law, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). The Office Action fails to make a case that the amount of experimentation necessary to make and use the invention would be undue, particularly in view of the fact that Applicants are using art-recognized techniques and methology. Therefore, Applicants respectfully request withdrawal of the rejection.

Claims 1 and 7-12 are rejected under 35 U.S.C. § 112, 1st paragraph, for lack of written description. Specifically, the Office Action indicates that the rejection is maintained because "none of the above claims has recited any function for the claimed products," (Office Action, page 3, lines 8-9). In addition, the Office Action indicates that the claims "fail to provide any function for the claimed polynucleotides" (Office Action, page 3, lines 11-12). Applicants respectfully traverse.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003). An applicant may show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. See *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613. See also MPEP 2163.

Sequences with 95% identity are readily determined using the standard methodology of molecular biology. On this basis alone, one skilled in the art can reasonably conclude that the inventor had possession of the claimed nucleotides of 95% identity to SEQ ID NO:1 by virtue of having SEQ ID NO:1. Applicants note that, unlike sequences in other patent applications which the Examiner may be using for comparison, the claimed nucleotide sequences are not being claimed on the basis of their ability to code for functioning proteins. As such, no guidance is necessary or warranted in terms of which nucleotides can be changed in order to maintain "functionality" for an encoded gene product.

However, even though Applicants believe no further guidance is necessary, the specification provides additional functional information for one skilled in the art. Numerous examples of DNA manipulation are provided by the specification, for example in Examples 1 and 2. Guidance on the performance of in situ hybridisation is also provided in Example 4, and the results of hybridisation with a variety of probes are presented in Examples 4 and 5. The Office Action even argues that hybridisation to SEQ ID NO:1 for sequences with 95% identity is an inherent attribute. As such, hybridisation of the claimed nucleotides to SEQ ID NO: 1 appears to be accepted by the Examiner.

The claims provide further functional information as amended. Upon entry of the amendment, claims 1 and 8 include the phrase "identifies bacteria involved in the biosynthesis of ecteinascidin compounds" as additional functional language. Hybridisation allows for the nucleotides such as SEQ ID NO:1 to be sequenced in order to identify an organism's taxonomic group, calculate related groups, and estimate rates of species divergence (see, for example, specification, page 12, lines 16-24). As stated in the specification, the

> [u]se of 16S rRNA gene sequences to identify bacteria is now the standard procedure for analysis of bacteria in environmental

> samples and has enabled much of the progress in the area of bacterial symbiosis

(see Specification, page 13, lines 9-13). Therefore, the nucleotide sequences of the present invention can be used in assays to identify endosymbionts of *Ecteinascidia* and to isolate their DNA, for example with walking chromosome techniques as described in the specification, for the identification of bacteria responsible for the biosynthesis of the ecteinascidin compounds, bioprecursors, or intermediates thereof (see specification, page 16, lines 27-31).

With respect to claims 8-9, the Office Action proposes a hypothetical DNA sequence of 3000 nucleotides with 30 nucleotides matching SEQ ID NO:1, and states that

> Such sequence may even hybridise under certain conditions to SEQ ID NO:1, but such DNA sequence is almost certainly not going to encode a product similar to 16S ribosomal RNA of this invention and therefore the genus of claimed probes and fragments of claims 8-9 remain rejected for lack of adequate structure and function

(Office Action, page 4, lines 2-5). If the Examiner is taking official notice that there is a DNA sequence with 3000 nucleotides with 30 nucleotides matching SEQ ID NO:1 that is capable of hybridizing to SEQ ID NO:1, Applicants respectfully request evidence of such a sequence or the reasoning behind the conclusion, or withdrawal of the statement for lack of support in the art. According to the MPEP, if Applicants challenge a factual assertion as not properly officially noticed, the Examiner must support the finding with adequate evidence (see MPEP 2144.03).

In view of the above, the claimed nucleotides have sufficient relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. Therefore, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-3732**, Order No. 13566.105017.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 13566.105017.

Respectfully submitted,
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By: _____

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